



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/218,913	12/22/1998	RODERICK L. HALL	98.736	2461

20306 7590 12/09/2003

MCDONNELL BOEHNEN HULBERT & BERGHOFF  
300 SOUTH WACKER DRIVE  
SUITE 3200  
CHICAGO, IL 60606

EXAMINER

NASHED, NASHAAT T

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	Application No. 09/218,913	Applicant(s) HALL ET AL.	
	Examiner Nashaat T. Nashed	Art Unit 1652	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED \_\_\_\_\_ FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 20 October 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: the amendment adds new claims 19-29 without canceling any other claims.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: none.

Claim(s) objected to: none.

Claim(s) rejected: 1-10, 14 and 16-18.

Claim(s) withdrawn from consideration: 11-13 and 15.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

  
NASHAAT T. NASHED PHD.  
PRIMARY EXAMINER

Claims 1-10, 14, and 16-18 are under consideration as they pertain to SEQ ID NO: 52.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 1-10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rasche *et al.* [IDS, paper number 16, reference number 7, *Arzneimittel-Forschung* 25 (1) 110-116 (1975)] for the reasons set forth in the prior Office actions.

Claims 3-10 are rejected under 35 U.S.C. § 103 as being unpatentable over Rasche *et al.* [IDS, paper number 16, reference number 7, *Arzneimittel-Forschung* 25 (1) 110-116 (1975)] in view of the state of the art for the reasons set forth in the prior Office actions.

Claims 14, and 16-18 are rejected under 35 U.S.C. § 103 as being unpatentable over Delaria *et al.* (J. Biol. Chem. 1997, 272 (18), 12209-12214) in view of the state of the art as exemplified by Rasche *et al.* [IDS, paper number 16, reference number 7, *Arzneimittel-Forschung* 25 (1) 110-116 (1975)], Fritz *et al.* (U. S. Patent 5,407,915), and O'Riordan *et al.* (IDS: Am. J. Respir. Crit. Care Med Vol. 155, pp. 1522-1528) for the reasons set forth in the prior Office actions.

In response to the above rejections, Applicants reiterated their previous arguments found in their response to the first Office action on the merit, filed March 26, 2003.

Applicants' arguments filed 10/20/03 have been fully considered but they are not deemed to be persuasive. Applicants have made no attempt to distinguish their claimed invention from that of the cited prior art, or provided any evidence to indicate or suggest that the method of the prior art is different and distinct from the claimed method. As indicated in the previous Office action, mailed on 6/18/02, the specification defines the phrase "mucocilliary dysfunction" as the inability of ciliated epithelium to clear mucus and sputum in lung airway which is a serious complication of chronic obstructive lung diseases such as chronic bronchitis (CB), bronchiectasis, asthma, and specially, cystic fibrosis (CF), see page 1, lines 14-17. Rasche *et al.* teach the use of aprotonin, a Kunitz-type serine protease, to treat an obstructive lung disease such obstructive bronchitis and emphysema, see the paragraph bridging pages 1 and 2. Also, they teach that a shortage of local protease inhibitors can arise in the bronchial area causing chronic obstruction in the airways for many years. The results obtained Rasche *et al.* clearly show that the application of the protease inhibitor relive the dysfunction and improve the patent conditions. It appears that the drop of in airway resistance and the liquefaction of viscous sputum are clinical observation resulting from accelerating mucocilliary clearance, i. e., increasing the clearance of mucus and sputum from the lung airway. Thus, the accelerating mucocilliary clearance is an intrinsic property that results of the method taught in the prior art. The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." In re Napier, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also In re Grasselli, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983). In addition, the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See also MPEP § 2112.01 with regard to inherency and product-by-process claims and MPEP § 2141.02 with regard to inherency and rejections under 35 U.S.C. 103. Applicants have not presented any evidence or indeed any argument indicating that the drop of airway resistance and the liquefaction of viscous sputum are not related to the acceleration of mucocilliary clearance.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, 13, and 16-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 15-18 of copending Application No. 09/441,966 (966) for the reasons set forth in the prior Office action, paper number 29.

In response to the above rejection, Applicants have not traversed the above rejection or filed a terminal disclaimer. They have requested to hold the rejection in abeyance until allowable subject matter is indicated. The rejection will remain on record until further action by the applicants.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

Serial Number: 09/218,913  
Art Unit: 1652

5

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Nashaat T. Nashed, Ph. D.  
Primary Examiner